

REMARKS

I. Introduction

Receipt of a final Office Action dated May 28, 2004, is acknowledged. In the Action, claims 23-25, 33, 37-39 and 47 were rejected as allegedly anticipated by Norris, U.S. Patent No. 4,957,686 ("Norris"), and claims 23-24, 27, 29, 33, 37, 38, 41, 43 and 47 were rejected as allegedly anticipated by Jones *et al.*, EP Patent No. 0414304 A2 ("Jones") or Day *et al.*, EP Patent No. 0403292 ("Day I"). Claims 23-30, 33, 35-44, 47 and 49-50 were also rejected as allegedly obvious over Day *et al.*, GB 2253859 ("Day II") and Merrill *et al.*, U.S. Patent No. 5,688,501 ("Merril").

Lastly, claims 31-32, 45-46, and 51-58 were objected to for being dependent on a rejected base claim but were considered allowable if rewritten in independent form.

Applicants respectfully request reconsideration of the present application in view of the reasons that follow.

II. Status of the Claims

In this response, applicants amended claims 31-32, 45-46, and 51-58 so as to not depend on a rejected base claim. Claim 37 was also amended to recite that each bacteriophage strain is effective in killing bacteria from at least 50% of bacterial isolates, which is a feature already searched and stated in claim 23.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested. Upon entry of this amendment, claims 23-33, 35-47, and 49-58 will be under examination.

III. Claim Rejections - 35 U.S.C. § 102

A. Rejection of claims 23-25, 33, 37-39 and 47 as allegedly anticipated by Norris, U.S. Patent No. 4,957,686

Claims 23-25, 33, 37-39, and 47 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Norris. In particular, the claims were rejected because “Norris . . . teach[es] or suggest[s] bacteriophages that are capable of infecting more than one strain of bacteria” and that “bacteriophages are taught to provide[] ‘extended protection against acid production by *L. acidophilis* or similar strains,’ thus teaching the bacteriophage to infect not only *L. acidophilis* but other strains as well.” Office Action at 3, emphasis omitted.

Further, the Office stated that “[w]ith respect to a single bacteriophage being able to infect a plurality of strains or species of bacteria, ATCC teaches known bacteriophage species that will infect Streptococcus group C bacteria[,] . . . [which] includes a plurality of strains and species of Streptococcus . . . , in addition to other bacterial species” *Id.* Applicants respectfully traverse this ground for rejection.

For a claim to be anticipated by a reference under 35 U.S.C. § 102, each and every element set forth in the claim must be found, either expressly or inherently, in the reference. If the reference fails to teach or suggest even one limitation of the claimed invention, then the claim is not anticipated. *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984).

Norris does not teach the presently claimed bacteriophage preparation having two or more bacteriophage strains, wherein each bacteriophage is selected against one of *staphylococci*, *hemophilii*, *helicobacter*, *mycobacterium*, *mycoplasmi*, *streptococci*, *neisserii*, *klebsiella*, *enterobacter*, *proteus*, *bacteriodes*, *pseudomonas*, *borrelii*, *citrobacter*, *escherichia*, *salmonella*, *propionibacterium*, *treponema*, *shigella*, *enterococci*, and *leptospirex*. Therefore, for this reason alone, Norris does not anticipate the claimed invention.

In addition, Norris’ cross reference to U.S. Patent No. 4,891,210 would also not anticipate the present invention. The ‘210 patent discloses that “bacteriophages are taught to

provide extended protection against acid production by *L. acidopholis* or similar strains” (Office Action, page 3, item 9), but the present invention does not claim a bacteriophage selected against any *Lactobacillus* strain, let alone “*L. acidopholis* or similar strains.”

Lastly, while the Office alleged that the cited ATCC bacteriophages are capable of infecting *Streptococcus* and *Lactobacillus*, the Office has not provided any specific evidence or explanation of record. Moreover, the Office has not provided any evidence that the cited bacteriophages meet each and every element of the claimed invention. Therefore, for at least these reasons, the rejection is improper and should be withdrawn.

B. Rejection of claims 23-24, 27, 29, 33, 37-38, 41, 43 and 47 as allegedly anticipated by Jones *et al.*, EP 0414304

Claims 23-24, 27, 29, 33, 37-38, 41, 43, and 47 are rejected under 35 U.S.C. § 102 (b) as allegedly anticipated by Jones. Specifically, the claims were rejected because “Unilever [Jones] teaches a method of growing bacteriophages that includes at least first and second inoculations” and therefore, “[t]he reference inherently anticipates the instantly claimed invention.” Office action at 5. Applicants respectfully request reconsideration and withdrawal of the rejection.

Claims 23-24, 27, 29, 33, 37-38, 41, 43, and 47 recite “[a] bacteriophage preparation [that]consists essentially of two or more bacteriophage strains, wherein each bacteriophage strain is specific for the bacterial infection treated and is selected against one of the group consisting of *staphylococci*, *hemophilii*, *helicobacter*, *mycobacterium*, *mycoplasmi*, *streptococci*, *neisserii*, *klebsiella*, *enterobacter*, *proteus*, *bacteriodes*, *pseudomonas*, *borrelii*, *citrobacter*, *escherichia*, *salmonella*, *propionibacterium*, *treponema*, *shigella*, *enterococci*, and *leptospirex*,” but Jones neither teaches nor suggests a bacteriophage preparation consisting of at least two or more bacteriophage strains. Therefore, the EP ’304 patent does not anticipate the claimed invention and applicants respectfully request that the rejection be withdrawn.

C. Rejection of claims 23-24, 27, 29, 33, 37-38, 41, 43 and 47 as allegedly anticipated by Day *et al.*, EP 0403292

Claims 23-24, 27, 29, 33, 37-38, 41, 43 and 47 are rejected under 35 U.S.C. § 102 (b) as allegedly anticipated by Day I. Specifically, the claims were rejected because “[t]he reference discloses bacteriophage preparations directed against ‘several species of bacterium’ defining a broad host range preparation and ‘specific for more than one family of bacterium.’” Office action at 6. In addition, the Office stated that “none of the claims [in the present application] require the administration of bacteriophage preparations . . . from a serial isolation process” and therefore, “[t]he reference inherently anticipates the instantly claimed invention.” *Id.* Applicants respectfully traverse this ground for rejection.

Day I is directed to preparations useful for “treatment and prophylaxis of low rumen pH-associated conditions in ruminants.” Day I at 2, lines 1-6. Specifically, Day I discloses preparations for reducing the production of lactic acid in the rumen, thereby restoring rumen pH for efficient digestion of cellulolytic and hemicellulolytic diet components. Day I at 2, lines 39-43, emphasis added.

Therefore, at best, Day I provides a preparation for “reduction of overall level of lactic acid in the rumen” but not a bacteriophage preparation wherein “each bacteriophage strain is effective in killing, *in vitro*, bacteria from at least 50% of bacterial isolates” as presently claimed. Accordingly, Day does not anticipate the claimed invention and withdrawal of the rejection is respectfully requested.

IV. Rejection of claims 23-30, 33, 35-44, 47 and 49-50 as allegedly over Day *et al.*, GB 2253859 in view of Merrill *et al.*, U.S. Patent No. 5,688,501

Claims 23-30, 33, 35-44, 47 and 49-50 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over GB 2253859 to Day *et al.* (“Day ‘859”) in view of Merrill *et al.*, U.S. Patent No. 5,688,501 (“Merrill”). Specifically, the claims were rejected because, *inter alia*, Day II “teach[es] the combination of two or more bacteriophages against two or more bacteria” and “Merrill *et al* teach clinically relevant bacteria for which bacteriophage preparations are available and are effective at the genus level for killing bacteria.” Office action at 8. Applicants respectfully traverse this ground for rejection.

To establish a *prima facie* case of obviousness, there must be: (1) some suggestion or motivation to modify the reference or to combine reference teachings, (2) a reasonable expectation of success, and (3) when combined, a teaching or suggestion of all the claim limitations in the prior art references. *See* MPEP §2143 (Aug. 2001). “Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant’s disclosure.” *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

A. The combination of Day II and Merrill does not teach administration of a bacteriophage preparation to a mammal suffering from bacterial infection

Day II discloses “preparations for the prevention and treatment of microbial infestations in food-stuffs.” Day II at 1, first paragraph, emphasis added. Moreover, Day II defines “food-stuffs” as “meat products, such as pate or sausage, or fish and/or vegetable preparations.” Day II at 2, sixth paragraph. Furthermore, Day II discloses “the use of the invention is generally preferred to be in connection with a dairy product, such as yogurt, but especially cheese.” Clearly, Day II discloses a preparation for treating microbial infestations in food products and therefore, a skilled artisan would not predict, with a reasonable expectation of success, that the disclosure of Day II could be applied to treating a mammal suffering from a bacterial infection.

In addition, there would not be a motivation to modify or combine the teachings of Day II with Merrill by virtue of the fact that the disclosure of Day II is limited to a preparation for the prevention and treatment of microbial infestations in food-stuffs. Indeed, Day II fails to teach or suggest administering a bacteriophage preparation for treating a mammal suffering from bacterial infection. The reason why the bacteriophage preparation in Day II was administered to a rat was to “meet the requirements of the limit test for acute oral toxicity described in Annex V of the EEC Commission Directive relating to the classification, packaging, and labeling of dangerous substances.” Day II at 9. Thus, neither Day II nor Merrill provide the incentive to a skilled artisan to modify Day II or combine Day II with Merrill so as to obtain the claimed invention.

B. The combination of Day II and Merrill do not teach a bacteriophage preparation wherein the bacteriophage is effective in killing

Furthermore, Day II fails to disclose a bacteriophage preparation wherein “each bacteriophage strain is effective in killing, *in vitro*, bacteria from at least 50% of bacterial isolates” as claimed in the present invention, and Merrill does not remedy these deficiencies. Merrill does not teach a virulent bacteriophage preparation selected on the bacteriophage’s ability to kill bacteria, as required by the claimed invention. Rather, Merrill discloses a method for producing bacteriophage that have increased resistance to inactivation by the treated animal’s host defense system and the bacteriophage of Merrill are able to survive longer in the host body as compared to the wild-type phage. Merrill at col. 5, lines 38-45. However, Merrill does not cure the deficiencies in Day II because Merrill also does teach or suggest bacteriophage having increased capabilities of killing bacteria. Therefore, the combination of Day II, in view of Merrill do not render the present invention obvious.

CONCLUSION

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing the claims in condition for allowance.

Applicants submit that the proposed claim amendments neither raise new issues nor necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined.

Finally, Applicants submit that the entry of the amendment would place the application in better form for appeal.

If there are any questions concerning this application, the Examiner is courteously invited to contact the undersigned.

Respectfully submitted,

Date November 29, 2004

By Michele M. Simkin

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5538
Facsimile: (202) 672-5399

Michele M. Simkin
Attorney for Applicant
Registration 34,717

Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.